

REMARKS

Claims 1-18 are pending and are rejected. Claim 19 is added.

Applicant thanks the Examiner for the courtesy of a telephone interview on April 25, 2002, discussing the amendments presented herein.

Applicant respectfully requests reconsideration of the Examiner's rejections for the following reasons.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112

Claims 1-18 are rejected under 35 U.S.C. § 112 ¶ 2 as indefinite. Applicant respectfully disagrees.

The phrase "an agent consisting essentially of" indicates that the composition does not include other hormones or other bioactive compounds (instant specification at least at page 3, lines 19-21, and page 5, lines 16-19).

The phrase "a response" indicates an optimum physiological replacement dose with a risk of side effects within an acceptable range (instant specification at least at page 5, lines 14-16).

The phrase "daily basis" refers to administration once a day, every day, as per a dictionary definition "daily" attached as Exhibit A: "1. Every day; 2. Once a day." Webster's II New College Dictionary, 285 (1999).

Regarding the phrase "at least one serially increased initial dose of said agent," applicant asserts that the method consists of replenishing human growth hormone in adults in an individualized manner. The specification discloses that an initial dose is

followed by at least one serially increased dose, determined by physical response as well as attainment of desired levels of IGF-1 (instant specification, at least at page 6, lines 6-8).

Regarding the phrases “said maintenance dose is administered monthly” or “said optimal dose is administered monthly,” applicant asserts that these indicate that the maintenance dose could be administered on a monthly, as opposed to a daily, basis. This is described at least at page 7, lines 1-9.

Regarding the term “about”, applicant respectfully asserts that it is not indefinite, in view of applicant's disclosure that the proper initial dosage for an individual is determined based on that individual's IGF-1 levels. The proper maintenance dosage for an individual is determined based on that individual's response to a previous dosage, as well as his/her IGF-1 levels, with a typical initial dosage of 2 µg/kg/day for a male and 4 µg/kg/day for a female, and a typical maintenance dosage in the range of 10-14 µg/kg/day for a male and 14-20 µg/kg/day for a female. Since gender also provides a means of determining the dose, applicant respectfully asserts the claimed doses are not indefinite.

Applicant has amended claims 11 and 12-17 to provide antecedent bases, as required.

Applicant thus believes the amended claims and above explanations fully overcome the rejections under 35 U.S.C. § 112.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102

Claims 1-18 are rejected under 35 U.S.C. § 102(b) as anticipated by Chein. Applicant respectfully disagrees.

Applicant's method of replenishing hGH comprises administering an agent consisting essentially of hGH, and excluding other hormones or other bioactive compounds. In contrast, Chein replenishes hGH as well as at least two other hormones that are below physiological levels. Thus, the agent administered in Chein's method consists of hGH and at least two other hormones.

Applicant's method of replenishing human growth hormone (hGH) is an individualized process. The maintenance dose of hGH is determined by evaluating the individual's response to serially increased doses of hGH every two to four weeks. If there is no response and IGF-1 levels are not optimal, the individual will receive a dose of hGH increased by an amount equal to the initial dosage, that is, serially increased.

In contrast, Chein teaches a method whereby each adult is monitored every thirty days for the sole purpose of determining whether the IGF-1 levels have reached a pre-determined amount. If they have not, the hGH dosage is increased by an uncertain amount until such pre-determined level is attained. Thus, Chein's method is neither individualized, nor are the dosages serially increased.

Applicant's method, once a desired maintenance dose is determined, allows the administration of hGH either on a daily or a monthly basis. In contrast, Chein's method requires the administration of the maintenance dose two times a day. Regarding the Examiner's suggestion that the term "once daily" be added to point out the difference, applicant respectfully asserts that the phrase "daily basis" is definite, as previously analyzed.

Attached hereto is a marked-up version of the changes made to the application by the current amendment.

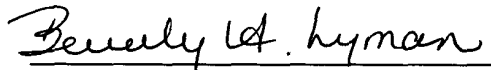
CONCLUSION

Applicant has submitted all fees believed to be necessary herewith. Should any additional fees or surcharges be deemed necessary, the Examiner has authorization to charge fees or credit any overpayment to Deposit Account No. 23-3000.

The Examiner is invited to contact the undersigned attorney if there are any questions or issues.

Respectfully submitted,

WOOD, HERRON & EVANS L.L.P.

A handwritten signature in cursive script, reading "Beverly A. Lyman", written over a horizontal line.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

Paragraph beginning at page 4, line 13 has been amended as follows:

A method is disclosed to replenish the age-related decline in human growth hormone (hGH) in adults by administering an individualized dosing regime of hGH in the absence of any other bioactive compounds. In the method, the individual initially receives incrementally increasing doses of hGH (inductive dose), while undergoing physiological and sociological assessment to determine the effect of hGH. Base[s]d on these outcomes, a maintenance dose to achieve the desired hGH replenishment for the individual is then determined. Thereafter, the individual receives this maintenance dose of hGH, either on a daily or monthly basis, depending upon his or her preference. Outcomes of this method of individualized hGH therapy include increased bone density, muscle and lean body mass, decreased fat body mass, improvement in serum lipid levels, for example, the ratio of "good" and "bad" cholesterol, improvement in skin tone and elasticity, improved cerebral function, improved sexual function, and an improved general sense of well being.

The Abstract has been amended as follows:

ABSTRACT

METHOD OF OPTIMIZING GROWTH HORMONE REPLACEMENT

A method to replenish human growth hormone (hGH) in a human adult.

[A] An initial daily dose of hGH is administered for three to four weeks, then an

individualized maintenance dose is determined by determining the individual's response to serially increased doses of the initial dose. The maintenance dose is then administered, usually in a microsphere formulation so that monthly dosing is possible. The method is useful to alleviate some of the effects of aging in mature adults.

IN THE CLAIMS

Claims 11, 12, and 17 have been amended as follows:

11. (AMENDED) The method of claim 10 wherein said [optimal] dose producing said optimal response is administered monthly.

12. (AMENDED) The method of claim 10 wherein bioavailability data are obtained [used to calculate said maintenance dose].

17. (AMENDED) The method of claim 16 wherein bioavailability data for said individual [is] are determined before administering said maintenance dose.

New claim 19 has been added.

EXHIBIT A

Webster's II

New College Dictionary



Houghton Mifflin Company

Boston • New York

M
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Webster's
pletely u
fast-chan
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DVD to

Webster's

Bi graphi
people fro

Geograph
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Charts and
on currency
more.

Style Guide
and punctua

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ist) *n.* A technician.
es.
killer cell.
sar, emperor. — see
ocrat. 3. Informal. On
zar's dom *n.*
.. An intricate Hung
sic for the czardas
tsarevich : tsar', cz
dest son.
vna : tsar', czar +
t'sa, -rét'') *n.* [Pol.
zar's wife.
em of government un

ARINA.

A native or resident
ie Czechs. — Czech

cts following the first

mal. Father.
n (-lɪz'əm) *n.* [Fr.] A w
ent (1916–23) that sou
the abolition of traditi
of comic derision in wh
e the guiding principl
is'tik) *adj.*
ther.
.. pl. daddy longleg
ngida, with a small; m
ie fly.

. datum, neuter p.p.
tural pedestal between
wall of a room, decor
panels. 3. a. A rectang
may be fitted into it. b.
oes. 1. To furnish with
a dado.
k. daidalos.] 1. Comple
employed.
dalos < daidalos, skill
nventor, builder of the
m (di-dá'le-ən, -dál')

4.
s. affodill < ME affod
DEL.] 1. a. A bulbous p
u. yellow flowers with
ver of the daffodil. 2. A

bs. daff, fool < ME daf
zy < a daff person>
ish < OE gedæfte, meek
ot. Frolicsome. — daff

k of matted or dung-co
Myth. The Babylonian

short pointed weapon
a dagger. b. Something
A double dagger.
lagōn < Heb. Dāgōn, dim
ient Philistines and late
l half-fish.
After Louis J. M. Dag
rotographic process with
ated metallic plate. 2. A

nure made by daguerreotype. — vt. -typed, -typ-ing, -types. To
make a daguerreotype of. — da-guerre'o-ty-p'er *n.* — da-
guerre'o-ty-p'y *n.*

dag-wood also **Dag-wood** (dāg'wōd') *n.* [After Dagwood Bum-
stead, a character who made such sandwiches in the comic strip
Blondie by Murat B. Young (1901–1973).] A multilayered sandwich
having various fillings.

dah (dā) *n.* A dash in Morse code.

dahlia (dāl'yə, dāl'-. dāl'-) *n.* [NLat. *Dahlia*, genus name, after
Anders Dahl (d. 1789).] 1. A plant of the genus *Dahlia*, indigenous to
Mexico and Central America, with tuberous roots and usu. large, var-
iously colored flowers. 2. The flower of a dahlia.

da-hoon (dā-hōon') *n.* [Orig. unknown.] An evergreen shrub or small
tree, *Ilex cassine* of the southeastern United States, having red fruit.

daily (dāl'yē) *adj.* [ME *daȳlic* < OE *dæglic* < *dæg*, day.] 1. Performed,
taking place, or appearing every day or weekday <a daily jog> 2. For
each day <a daily telephone record> 3. Day-to-day; everyday <an
appliance for daily use> — *adv.* 1. Every day <Take exercise daily>
2. Once a day <Wind your watch daily> — *n., pl. -lies.* A newspaper
published every day or every weekday.

daily double *n.* A bet won by selecting both winners of two spec-
ified races on one day, as in horse racing.

dai-mi-o also **dai-my-o** (di'mē-ō', dim'yō') *n., pl. daimio or*
-mis also daimyo or -my-os. [J. *daimyo* : dai, great < Chin.
dai> + *myo*, name < Chin. ming>.] A hereditary nobleman in Japan's
feudal period.

dai-mon (di'mōn') *n.* var. of DEMON 3, 4.

dain-ty (dān'tē) *adj. -ti-er, -ti-est.* [ME *deinte*, excellent <
deinte, excellence, dignity < OFr. *deintie* < Lat. *dignitas* < *dignus*,
worthy.] 1. Delicately beautiful : EXQUISITE. 2. Delicious : choice. 3.
Of refined taste : DISCRIMINATING. 4. Overfastidious. — *n., pl. -ties.*
A delicacy. — **dain'ti-ly** *adv.* — **dain'ti-ness** *n.*

dai-qui-ri (di'kə-rē, dāk'ə-) *n., pl. -ris.* [After *Daiquiri*, Cuba.] An
iced cocktail of rum, lime or lemon juice, and sugar.

dairy (dār'yē) *n., pl. -ies.* [ME *daierie* < *daie*, dairymaid < OE
daige.] 1. A commercial establishment that processes or sells milk and
milk products. 2. A place where milk and cream are stored and pro-
cessed. 3. A dairy farm. 4. The dairy business.

dairy cattle *pl. n.* Cows bred and raised for milk.

dairy farm *n.* A farm for producing milk and milk products.

dairy-ing (dār'yē-ing) *n.* The business of a dairy.

dairy-maid (dār'yē-mād') *n.* A woman who works in a dairy.

dairy-man (dār'yē-mən) *n.* 1. A dairy manager or owner. 2. A man
who works in a dairy.

da-is (dā'is, dās) *n.* [ME *deis* < OFr., platform < LLat. *discus*, table.
— see DISK.] A raised platform, as in a lecture hall, for honored guests
or speakers.

A word history: *Dais* is a word that was borrowed into English
twice. It first appeared in the 13th century as *deis*, from Old French
deis, indicating a table raised on a platform at which honored guests
were seated. *Deis* was also used of the platform alone. This word died
out in England in the 16th century; it survived, however, in Scotland
with the meaning "bench." In the late 18th century historical writers
revived the word. Although they used the modern French spelling
dais, the appearance of *dais* probably represents a borrowing from Eng-
lish itself rather than from French, because the modern French word
means only "canopy." The French forms *deis* and *dais* are ultimately
derived from Latin *discus*, which in medieval times meant "table."
Dais is thus cognate with *disk*, *dish*, and *desk*.

dai-sy (dā'sē) *n., pl. -sies.* [ME *daisie* < OE *dægesæge* : *dæg*, day
+ *æge*, eye.] 1. A plant having rayed flowers, esp. a widely naturalized
European plant, *Chrysanthemum leucanthemum*, having flowers with
a yellow center and white rays. 2. A low-growing European plant, *Bel-
lula perennis*, having pink or white rayed flowers. 3. The flower of a
daisy. 4. Slang. Something excellent or notable.

A word history: The name *daisy*, a compound word meaning
"day's eye," was originally applied to the European plant *Bellis peren-
nis*, which is called in the United States the *English daisy*. The term
"day's eye" is especially appropriate to this plant because it folds its
petals at night and opens them in the morning with the sun, like an
eye that sleeps and wakes.

Da-kin's solution (dā'kinz) *n.* [After Henry Drysdale Dakin
(1880–1952).] A dilute sodium hypochlorite solution used in cleansing
wounds.

Da-ko-ta (dā-kō'tə) *n., pl. Dakota or -tas.* 1. A member of any of
the Sioux peoples, esp. any of the eastern branch peoples located in
Minnesota, eastern Nebraska, and the eastern Dakotas. 2. The Siouan
language of the Dakota. — **Da-ko'tan** *adj. & n.*

Da-lai La-ma (dā'li lā'mā) *n.* [Tibetan : Mongolian *dalai*, ocean +
Tibetan *bla-ma*, monk.] The traditional governmental ruler and high-
est priest of the Lamaist religion in Tibet and Mongolia.

dal-a-pon (dāl'ə-pōn') *n.* [Blend of DI-, ALPHA, and PROPIONIC ACID.]
An organic acid used as a herbicide.

da-la-si (dā-lā'sē) *n., pl. dalasi.* [Native word in Gambia.] — See
table at CURRENCY.

dale (dāl) *n.* [ME < OE *dæl*.] A valley.

da-leth (dā'lēth', -lēt') *n.* [Heb. *dāleth* < *dālt*, door.] The fourth let-
ter of the Hebrew alphabet. — See table at ALPHABET.

dalles (dālz) *pl. n.* [Fr., pl. of *dalle*, gutter < OFr. < ON *dæla*.] The
steep precipices forming the sides of a gorge or narrow valley, usu. hav-
ing rapids at the bottom.

dali-ance (dāl'ē-əns) *n.* 1. Frivolous action : dawdling. 2. Playful
flirtation.

Dal-lis grass (dāl'is) *n.* [Prob. alteration of *Dallas*, Texas.] A South
American grass, *Paspalum dilatatum*, grown in the southern United
States for pasturage.

dall-y (dāl'yē) *v. -lied, -ly-ing, -lies.* [ME *dalien* < OFr. *dali-er*.]
— *vi.* 1. To play amorously : FLIRT. 2. To trifle. 3. To waste time :
DAWDL. — *vt.* To waste (time). — **dāl'li-er** *n.* — **dāl'ly-ing-ly**
adv.

Dal-ma-tian (dāl-mā'shən) *n.* A dog believed to have been bred
orig. in Dalmatia, having a short, smooth white coat covered with
black or dark-brown spots.

dal-mat-ic (dāl-māt'ik) *n.* [ME *dalmatik* < Med. Lat. *dalmatica* <
Lat. *dalmaticus*, Dalmatian.] 1. A wide-sleeved garment worn over the
alb by a deacon, cardinal, bishop, or abbot at Mass. 2. A wide-sleeved
coronation garment worn by an English monarch.

dal se-gno (dāl sän'yō) *adv.* [Ital., from the sign.] Mus. From a place
marked by the sign § to a designated point. — Used as a direction to
repeat a passage.

dal-ton (dōl'tən) *n.* [After John Dalton (1766–1844).] Atomic mass
unit.

dal-ton-ism also **Dal-ton-ism** (dōl'tə-niz'm) *n.* [After John
Dalton (1766–1844).] Red-green colorblindness. — **dal-to'ni-an**
(dōl-tō'nē-ən), **dal-ton'ic** (-tōn'ik) *adj.*

dam (dām) *n.* [ME.] 1. A barrier built across a waterway to control the
flow or raise the level of water. 2. A body of water controlled by a dam.
3. An obstruction : hindrance. — *vt.* **dammed, dam-ming, dams.**

1. To build a dam across or hold back by a dam. 2. To obstruct or
restrain : CONFINE.

dam² (dām) *n.* [ME *dam*, *dame*. — see DAME.] 1. A female parent.
— Used of a quadruped. 2. Archaic. A mother.

dam-age (dām'ij) *n.* [ME < OFr. < *dam*, loss < Lat. *damnum*.] 1.
Impairment of the usefulness or value of person or property : HARM. 2.
damages. Law. Money to be paid as compensation for injury or loss.
3. Informal. Cost : price. — *v.* **-aged, -ag-ing, -ag-es.** — *vt.* To
cause injury to : HARM. — *vi.* To suffer or be susceptible to damage.
— **dam'age-a-ble** *adj.* — **dam'ag-ing-ly** *adv.*

dam-ar (dām'ər) *n.* var. of DAMMAR.

dam-as-cene (dām'ə-sēn', dām'ə-sēn') *vt. -cened, -cen-ing,*
-cenes. [OFr. *damasquiner* < *damasquin*, of Damascus.] To decorate
(metal) with wavy inlaid or etched patterns. — **dam'as-cene'** *n.* &
adj. — **dam'a-scen'er** *n.*

Damas-cus steel (dā-mās'kəs) *n.* An early form of steel with
wavy markings, developed in Near Eastern countries, esp. Persia, and
used primarily in sword blades.

dam-ask (dām'ask) *n.* [ME < Med. Lat. (*pannus de*) *damasco*, (cloth
of) Damascus.] 1. A rich patterned fabric of cotton, linen, silk, or wool.
2. A fine, twilled table linen. 3. Damascus steel. 4. The wavy pattern
on Damascus steel. — *vt.* **-asked, -ask-ing, -asks.** 1. To dama-
scene. 2. To decorate or weave with rich patterns.

damask rose *n.* [*< obs. Damask*, Damascan, Damascus.] A rose in-
digenous to Asia, *Rosa damascena*, with sweet-smelling red or pink
flowers used as a source of attar.

damask steel *n.* Damascus steel.

dame (dām) *n.* [ME < OFr. < Lat. *domina*, fem. of *dominus*, lord,
master.] 1. A title once given to a woman in authority or to the mis-
tress of a household. 2. A married woman : MATRON. 3. Slang. A wom-
an. 4. Chiefly Brit. a. Archaic. The legal title of the wife or widow of
a knight or baronet. b. A title of a woman equivalent to that of a
knight.

dame's rocket *n.* A plant indigenous to Europe, *Hesperis matron-
alis*, with fragrant purple or white flower clusters.

dame's violet *n.* Dame's rocket.

da-min-o-zide (dā-mīn'ə-zid') *n.* [D(IMITHYL) + AMINO- + (HY-
DRA)Z(INE) + -IDE.] A chemical plant growth regulator, C₆H₁₂N₂O₃,
used commercially on apples to retard growth, enhance color, and in-
crease storage life.

dam-mar or **dam-ar** also **dam-mer** (dām'ər) *n.* [Malay *damar*,
resin.] Any of various hard resins obtained from Indo-Malayan trees of
the genera *Shorea*, *Balanocarpus*, and *Hopea* and used in varnishes and
lacquers.

damn (dām) *v. damned, damn-ing, damns.* [ME *dampnen* < OFr.
dampner < Lat. *dampnare*, to condemn, inflict loss upon < *dammum*,
loss.] — *vt.* 1. To pronounce an adverse judgment on. 2. To bring about
the failure of : RUIN. 3. To condemn as injurious, illegal, or immoral
<damn drugs and alcohol> 4. To condemn to eternal punishment :
DOOM. 5. To swear at by using the word "damn." — *vi.* To swear :
curse. — *interj.* — Used to express anger, irritation, contempt, or dis-
appointment. — *n.* 1. The saying of "damn" as a curse. 2. Informal. A

t ē be hw which
v, for oi noise

th boot ou out th thin th this ū cut ūr urge y young
ph abuse zh vision ə about, item, edible, gallop, circus